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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,506	10/17/2001	Gregory R. Chiklis	19383-014	6911

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EXAMINER

WANG, LOUISE Z

ART UNIT PAPER NUMBER

1648

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/981,506	Applicant(s) CHIKLIS ET AL.	
	Examiner Louise Wang	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-63, 65, 66, 68 and 69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 2-63, 65, 66, 68, and 69 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

HC

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The examiner of your application in the Patent and Trademark Office has been changed. In order to aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Louise Wang, Art Unit 1648.

Upon a review of the prosecution history in this application, the Office has determined that it is necessary to vacate the previous Office action. In order for examination to further proceed expeditiously and with high quality, a restriction requirement is necessary as set forth below. The Office regrets any inconvenience this may cause Applicant.

DETAILED ACTION

Applicant's Amendment, filed January 21, 2005, is acknowledged.

Claims 1, 64, and 67 have been canceled.

Claims 2-63, 65, 66, 68, and 69 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-9, 12-17, 49-57, and 60-63, drawn to a non-pathogenic microorganism comprising surface proteins and substantially intact nuclear components, wherein the surface proteins are covalently attached to a compound, a composition of matter comprising the microorganism and a liquid matrix, and a kit comprising the microorganism, classified in class 435, subclass 245.
- II. Claims 10-17, 49, and 58-63, drawn to a non-pathogenic microorganism comprising surface proteins and substantially intact nuclear components, wherein

the surface proteins are partially digested by an enzyme, a composition of matter comprising the microorganism and a liquid matrix, and a kit comprising the microorganism, classified in class 435, subclass 245.

- III. Claims 18-26 and 30-33, drawn to a method for producing a non-pathogenic microorganism comprising surface proteins and substantially intact nuclear components, wherein the surface proteins are covalently attached to a compound, classified in class 435, subclass 245.
- IV. Claim 18, 28 and 29, drawn to a method for producing a non-pathogenic microorganism comprising surface proteins and substantially intact nuclear components, wherein the surface proteins are partially digested by an enzyme, classified in class 435, subclass 245.
- V. Claims 34-42, 45-48, 65, and 68, drawn to a method for detection of a microorganism, comprising addition of a purified control microorganism wherein the surface proteins are covalently attached to a compound, classified in class 435, subclass 5.
- VI. Claims 34, 43-48, 66, and 69, drawn to a method for detection of a microorganism, comprising addition of a purified control microorganism wherein the surface proteins are partially digested by an enzyme, classified in class 435, subclass 5.

The inventions are distinct, each from the other because:

Inventions I and II are distinct from each other because of their surface protein modifications. The surface proteins of Invention I have covalently attached chemical compounds whereas the surface proteins of Invention II are partially degraded. These modifications render Inventions I and II with different chemical properties as well as affect binding specificities and mechanisms, thus each invention represents a patentably distinct subject matter.

Inventions (I, II) and Inventions (V, VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the surface-modified microorganisms as claimed in Inventions I and II can be used in a different method such as the therapeutic treatment of diseases, whereas the method of detection as claimed in Invention III and IV can use a hybridization probe, an aptamer, or an antibody.

Inventions III-VI are different methods with respect to starting materials, physiological mechanisms, and end products; therefore, each method is patentably distinct.

Inventions (III, IV) and Inventions (I, II) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the chemical modification methods as claimed in Inventions III and IV can be used to make derivatives of pharmaceutical drug compounds or any proteins.

These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Furthermore, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed invention:

If Applicant elects one of Groups I, III, and V, Applicant is required to select a specific chemical compound as exemplified by claims 4, 5, 7-9, 21, 23, 25-27, 37, 39-42, 52, and 54-57. These species are distinct because their structures, physicochemical properties and modes of action are different. Furthermore, the examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these Species together.

If Applicant elects one of Groups II, IV, and VI, Applicant is required to select a specific enzyme as exemplified by claims 11, 29, 44, and 59. These protein species are distinct because their amino acid sequences, structures, and/or modes of action are different; thus, each enzyme represents patentably distinct subject matter. Furthermore, the examination of these species

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would require different searches in the scientific literature, which would not be coextensive. As such, it would be burdensome to search these species together.

Additionally, for all of the above Groups, Applicant is required to select a specific microorganism as exemplified by claims 15, 17, 31, 33, 46, 48, 61, and 63. These species are distinct because their cellular components, surface proteins, structures, mechanisms of replication, and modes of infection are different. Furthermore, the examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these Species together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the**

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patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Contact Information

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR


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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Louise Wang
July 22, 2005


JEFFREY STUCKER
PRIMARY EXAMINER